

## REMARKS

Upon entry of the amendments, claims 9, 11-21, 23-29, and 31-48 are pending. Claims 23 and 24 have been amended to change the dependencies. Claims 17-20 and 36-48 have been withdrawn and claims 1-8, 10, 22 and 30 have been cancelled without prejudice. Applicants respectfully submit that no new matter has been added.

### ***Claim Rejections Under 35 U.S.C. § 103(a)***

Claims 1, 3-9, 11-16, 21, 23-29 and 31-35 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Application Publication No. 2004/0248972 to Lockhart et al. ("Lockhart"). In the interest of furthering prosecution, and without acquiescing that the rejection has merit, Applicants have cancelled claims 1 and 3-8. The Examiner alleges that "Lockhart et al. teach the use of the claimed statin compounds for the treatment of visual disorders, such as glaucoma." Office action, at page 4. Applicants respectfully disagree and submit that the Examiner has mis-characterized the disclosure of Lockhart for the reasons stated in the prior response. See response filed by Applicants on November 3, 2010.

Furthermore, Lockhart was filed on May 17, 2004 and claims priority to U.S. provisional application Serial No. 60/471,425 which was filed on May 16, 2003. Hence, the effective date of Lockhart is May 16, 2003. Without acquiescing to the propriety of the rejection and without prejudice to pursuing the subject matter in a later application, Applicants submit herewith a declaration under 37 CFR 1.131 ("the 131 Declaration") by Vasanth Rao, one of the inventors of the claimed invention.

The 131 Declaration establishes that prior to the effective date of the Lockhart reference, the inventors conceived of the invention as presently claimed, i.e., a method of treating or inhibiting the progression of glaucoma, a method of treating glaucoma or a method of controlling normal or elevated intraocular pressure comprising administering to a patient in need thereof a compound that inhibits the HMG-CoA reductase-catalyzed transformation of HMG-CoA to mevalonic acid, wherein said compound is administered in an amount sufficient to effect said treatment or inhibition, and wherein said compound is a statin. See paragraph 4 of the 131 Declaration.

Moreover, the 131 Declaration establishes that prior to the effective date of the Lockhart reference, the inventors reduced to practice the claimed invention. See paragraphs 5 and 6 of the 131 Declaration. The 131 Declaration establishes that prior to the effective date of the Lockhart reference, it was known that elevated intraocular pressure commonly associated with

glaucomatous conditions may be a consequence of impairments in trabecular meshwork (TM) function, i.e., the impairment of drainage of aqueous humor from the eye. It was also known that changes in cell shape, i.e., rounding up of cells, and decreases in actin stress fibers and myosin light chain phosphorylation in TM cells correlate well with increased cell relaxation and increased outflow facility. Furthermore, it was also known that compounds that caused changes in cell shape and decreases in actin stress fibers and myosin light chain phosphorylation in TM cell could be used as a treatment for glaucoma. Attached to the 131 Declaration as Exhibit A is a journal article showing the state of the art at the time of the invention.

The 131 Declaration establishes that prior to the effective date of the Lockhart reference, the inventors determined that statins affect cell shape, i.e., cause rounding up of cells, decrease actin polymerization and relaxation of cells depolymerize actin stress fibers and decrease myosin light chain phosphorylation in different cell types including TM cells, thus showing that statins could be used as a treatment for glaucoma. As evidence of reduction to practice, attached to the 131 Declaration as Exhibits B and C are an email written by Inventor Vasanth Rao and lab notebook pages showing control and 30  $\mu$ M lovastatin-treated TM cells after 24 hours.

Applicants have thus established prior conception and reduction to practice prior to the effective date of the Lockhart reference. Therefore, Lockhart should be removed as a reference. Withdrawal of the rejection of claims 9, 11-16, 21, 23-29 and 31-35 is respectfully requested

### **CONCLUSION**

Applicants submit that the claims are patentable in light of the amendments and remarks presented herein. Applicants respectfully request allowance of the claims. The Examiner is invited to contact the undersigned attorney with any questions, comments, or suggestions relating to the above-identified patent application.

Respectfully submitted,

/charlene l yager/  
Charlene L. Yager  
Reg. No. 48,887

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Michael Best & Friedrich LLP  
100 East Wisconsin Avenue, Suite 3300  
Milwaukee, Wisconsin 53202-4108  
(414) 271-6560